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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,177	12/22/2005	Orna Mor	69664-A-PCT-US/JPW/JW	8039

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	PAPER NUMBER
1652	
MAIL DATE	DELIVERY MODE
09/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,177	MOR ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-55* is/are pending in the application.

4a) Of the above claim(s) *47-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/5/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. ***Election***

Applicant's election of Group I (claims 36-46) with traverse, in reply filed 6/30/2008, is acknowledged. The traversal is on the ground(s) that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Groups II and III would not impose a serious burden once the prior art relevant to Group I has been identified. Therefore, there would be no serious burden on the Examiner to examine Groups I-III together in the subject application.

Applicants' arguments are considered but not found to be persuasive because Group II is directed to a pharmaceutical composition comprising an inhibitor of any HNOEL-iso polypeptide (neuronal olfactomedin-related endoplasmic reticulum localized protein isoforms), which is not the elected group and Group III involves an entirely different method than Group I.

Applicants' arguments regarding species election is reconsidered and found to be persuasive. Accordingly, the elected claims 36-46 of Group I will be examined in full without a species election requirement.

2. Claims 36-46 are under consideration in this Office Action.

3. **Claims withdrawn** :

Claims 47-55 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. This application filed under 35 USC 119(e) lacks the necessary reference to the prior application. This application claims the benefit of US Provisional Application No. 06/ , filed ..., should be entered following the title of the invention or as the first sentence of the specification. Also, the present status of all parent applications should be included.

5. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification

6. ***Written Description***

Claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a method for treatment of a fibrosis related pathology in a subject in need of such treatment comprising administering to the subject a genus of inhibitor(s) of HNOEL-iso polypeptide(s) sufficient to effect a substantial inhibition of the HNOEL-iso polypeptide(s) wherein the inhibitor compounds or the HNOEL-iso polypeptide(s) are a large genus with no defined structure (claim 36). Claims 37-43 specifies the fibrosis related pathology to be liver fibrosis, pulmonary fibrosis, kidney fibrosis, cardiac fibrosis, scarring fibrosis or a nephropathy condition. Claims 44-46, describes the inhibitor to be an antibody, siRNA or an anti-sense oligonucleotide corresponding to HNOEL-iso polynucleotide.

The specification provides specific amino acid and nucleic acid sequences of human HNOEL-iso polypeptide of SEQ ID NO: 2 and SEQ ID NO: 1 respectively, as the target(s) to be inhibited in order to solicit an inhibition response. However, the response is not correlated to any of the fibrosis related pathology or nephropathy condition. No specific antibodies or antisense oligonucleotides (claims 44 & 46) have been exemplified to be effective in inhibition of any of the listed conditions. Silencing RNA (siRNA) molecules that decrease or silence (prevents) the expression of gene/mRNA of its endogenous or cellular components, are described in the sequences of SEQ ID Nos. 3-7, are the only effective compounds. Expression of HNOEL: In cells which express HNOEL endogenously (Rat cells), it was shown that the expression of HNOEL was decreased 40-70% when any one of the above siRNAs was transiently transfected into the cells. This was determined on the mRNA level, as tested by semi-quantitative RT-PCR. These experiments were repeated with cells which over-express exogenous HNOEL (kidney epithelial cells strain 293) with essentially the same results (example 15, amendment to specification filed 8/1/2007). No experimentation is described for the numerous other specific conditions listed in the claims.

The term "treatment' as used herein refers to administration of a therapeutic substance effective to ameliorate symptoms associated with a disease, to lessen the severity or cure the disease, or to prevent the disease from occurring (page 11 of the specification). No therapeutic compounds have been discovered or have been shown to be effective curing any disease. At the most these are screening assays performed to *identify compounds* that may be useful in *treating a disease not curing the disease*. Example 14 (amendment to specification filed 8/1/2007), describes polyclonal antibodies against two peptides - Peptide 1: Ac-CQDQS SRHAA ELRDF KNK-NH2, located at amino acid residues 44-61 (SEQ ID NO: 8); Peptide 2: Ac-LDPQT LDTEQ QWDTP C-NH2, located at amino acid residues 301-316 (SEQ ID NO: 9) which may be used in the method of the invention.

The specification only provide by name or structure of the antibodies, however, do not show the effects on the expression of the HNOEL-iso polypeptide or DNA; nor provide any evidence of the effectiveness of the specific inhibitor compound in treating the specific fibrosis related condition(s). The effective function(s) of the candidate compound(s) in relation to the specific disease remain undescribed. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Written description requirement of 35 U.S.C. §112 cannot be satisfied by merely providing the desired function of the compound without more detail on the compound's structure, chemical formula, chemical name, or physical properties [*University of Rochester v. G.D. Searle & Co. Inc.* Page 427, see details below**]. The specification discloses a few details of the compound(s) structure or chemical name, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

A method patent for treating the side effects of pain relievers is invalid for failing to adequately describe the compound used in the claimed method, the U.S. District Court for the Western District of New York rules. Granting a summary judgment motion, the

court reasons that the written description requirement of 35 U.S.C. §112 ¶1 cannot be satisfied by merely providing the desired function of the compound without more detail on the compound's structure, chemical formula, chemical name, or physical properties. The court also stresses the applicability of the written description requirements to the compound used, even though the patent consists of method claims rather than compound claims. *University of Rochester v. G.D. Searle & Co. Inc.* 249 F. Supp. 2d 216 [**68 USPQ2d 1424**] (W.D.N.Y. 2003). 249 F. Supp. 2d 216 [**68 USPQ2d 1424**] (W.D.N.Y. 2003).]

7. ***Enablement Rejection***

Claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a fibrosis related pathology in a subject using a inhibitor(s) of the HNOEL-iso polypeptide(s) (SEQ ID NO: 2), in the form of a specific antibody prepared against SEQ ID NO: 8 or 9, or a siRNA inhibitor which is specific to HNOEL-iso polynucleotide of SEQ ID NO: 3 thru SEQ ID NO: 7, does not reasonably provide enablement for any method for treatment of a fibrosis related pathology in a subject in need of such treatment comprising administering to the subject a genus of inhibitor(s) of HNOEL-iso polypeptide(s) sufficient to effect a substantial inhibition of the HNOEL-iso polypeptide(s) using any inhibitor of the HNOEL-iso polypeptide(s) (claim 36). Claims 37-43 specifies the fibrosis related pathology to be liver fibrosis, pulmonary fibrosis, kidney fibrosis, cardiac fibrosis, scarring fibrosis or a nephropathy condition. Claims 44-46, describes the inhibitor to be an antibody, siRNA or an anti-sense oligonucleotide corresponding to HNOEL-iso polynucleotide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims does not commensurate with the enablement provided by the disclosure with regard to the extremely large number of inhibitor(s) to be an antibody to any HNOEL-iso, siRNA to any HNOEL-iso polynucleotide or an anti-sense oligonucleotide to nay HNOEL-iso polynucleotide broadly encompassed by the claims.

The specification provides guidance to the occurrence of preparation of specific antibodies to HNOEL-iso (SEQ ID NO: 8 or 9) & specific siRNA to SEQ ID No. 3-7. The specification and the prior art also teach the expression of HNOEL-iso polypeptide in various tissues of human and rat. There are no studies in the instant specification to support the claim that inhibitor(s) to an antibody, siRNA or an anti-sense oligonucleotide corresponding to any HNOEL-iso and/or the encoding polynucleotide be effective in treating all the fibrosis related or nephropathy condition. The prior art is also devoid any teachings that would lend support to enable the broad scope of the claims considering the limited guidance provided in the instant specification.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of exact nature of the treatment method having the desired characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-46 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how is the inhibition measured ?

9 No claim is allowed.

10. The following art (abstract only) is cited out of interest but has not been used in any art rejection: CN 1283692 (Chinese) **[Liu, Feng et al.]**

PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
CN 1283692	A	20010214	CN 2000-111693	20000217
PRIORITY APPLN. INFO.:			CN 2000-111693	20000217

AB The invention provides cDNA sequences of a novel human neuronal olfactomedin-related endoplasmic reticulum localized protein isoform hNOEL-iso cloned from human dendritic cell. The invention also relates to constructing hNOEL-iso gene expression vectors to prepare recombinant hNOEL-iso protein using Escherichia coli cells or eukaryotic cells. Methods of expressing and preparing recombinant hNOEL-iso protein and its antibody are described.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571) 272 0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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